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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,625	11/02/2001	Gerardo Castillo	PROTEO.P18	5292

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EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 12/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,625	CASTILLO ET AL.	
	Examiner	Art Unit	
	Christopher R. Tate	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 October 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,31 and 33-52* is/are pending in the application.

4a) Of the above claim(s) *40-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,31 and 33-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election of Group X, claims 18, 31, and 33-39, in the response filed October 1, 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Newly submitted claims 40-51 are directed to one or more inventions that is/are independent or distinct from the elected invention originally claimed for the following reasons: The invention of Group X requires a series of particular extraction/processing steps which are either different and distinct from those recited in the methods of claims 40 and 49 or do not necessarily require the same working parameters as those recited within the methods of claims 40 and 49. Accordingly, claims 40-51 are withdrawn from consideration as being directed to a non-elected invention by original presentation with respect to the elected invention of Group X (see, e.g., 37 CFR 1.142(b) and MPEP § 821.03).

Claims 18, 31, and 33-39 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18, 31, and 33-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is rendered vague and indefinite for the following reasons:

- Step (c) is unclear by the phrase "about 3 times as steps a and b above". Is this attempting to define that steps (a) and (b) are repeated three times. If so, this should be clearly defined in step (c).
- Typically, the use of parentheses – e.g., in steps (d), (e), (j), (k), (l), (m) - encompassing terminology in the claims is indefinite because it is unclear if what is stated in parentheses is a further limitation or simply alternative meaning. Please note that the parenthetical phrases within step (q) showing the approximate collection minutes for each recited fraction are not considered indefinite.
- Step (g) recites the limitation "the solid material". There is insufficient antecedent basis for this limitation in the claim. It is suggested that step (f) be expanded upon by reciting --to form a solid material-- at the end of this step.
- Step (i) appears to be incomplete because it is unclear as to what portions are being defined therein – e.g. portions of what? It is suggested that the phrase --of the solubilized extract-- be inserted after the term "portions".
- Step (k) is very confusing, as drafted, in part because it appears to be incomplete – e.g., it is unclear as to how the set of active fractions are actually obtained (and how they differ from the final fractions of step q) as well what type of activity the active fractions are being assayed for with respect to collecting the "active fractions".
- In steps (l) and (m), the parentheses should be removed (as discussed above) for clarity. It is also suggested that the word "whereby" be inserted after the terms "solvent A" and "solvent B", respectively.

- Step (o) appears to be incomplete because it is unclear as to what is being injected multiple times – is it the lyophilized eluant or something else?
- Step (p) is grammatically awkward. For consistency, it is suggested that the term "minutes" throughout this step be placed after the numerical ranges therein. In addition, it is suggested that the term "where" be replaced by --whereby--.
- In step (q) the phrase "separating and collecting at least one fractions component selected from the group of fraction components defined as fraction" is very unclear and confusing. In particular the plural recitation "fractions", as well as the redundant and confusing terms "component" and "components" after the respective phrases "fractions" and "fraction" make this phrase vary unclear. It is suggested that this phrase be amended to recite --separating and collecting at least one fraction selected from the following fractions:-- (as well as amending the preamble accordingly) to overcome this rejection.

Claim 31 is exceedingly vague and indefinite by the phrase "pharmaceutical agent comprising a therapeutically effective amount of a material made according to the process of claim 18" (lines 1-2) because it is totally unclear as to what material from claim 18 is being defined thereby – e.g., is the material of claim 31 attempting to define the solid material obtained in step (f) and used in step (g); is it the set of active fractions obtained in step (k), is it one or more of the fractions obtained in step (q) or something else? Please note that other than the step (f)-(g) solid material, the term "material" in claim 31 lacks antecedent basis with claim 18. It would appear that Applicants actually intend the pharmaceutical product of claim 18 to comprise a therapeutically effective amount of one or more of the final separated, collected fractions obtained in step (q) of claim 18. As such, this should be clearly defined in step 31 (especially

since these final separated, collected fractions are considered essential elements of the pharmaceutical product of claim 31, based upon the overall teachings of the instant specification – see, e.g.., MPEP 2172.01). In addition, "pharmaceutical agent comprising" is unclear and confusing because this would imply a singular agent, whereas it would seem more appropriate and clear to define the claimed product as a pharmaceutical composition comprising a therapeutically effective amount of one or more of the fractions obtained in step q of claim 18.

Claim 35 is rendered vague and indefinite for the following reasons:

- the phrase "the amyloidosis" is recited numerous times throughout claim 35. There is insufficient antecedent basis for this limitation in the claim.
- the metes and bounds of the ambiguous phrase "various forms of malignancy and Familial Mediterranean Fever" are not clearly delineated – e.g., what forms?
- the linking terms "including" and "such as" are unclear and indefinite – i.e., a broad range or limitation followed by linking terms (for example, preferably, including, such as, for instance, especially) and a narrow range or limitation within the broad range or limitation is considered indefinite since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired (see MPEP 2173.05(c) for additional information).
- the phrase "the alpha-synuclein associated disease" lacks antecedent basis.
- the overall phrase "and the alpha-synuclein associated disease is selected from Parkinson's disease and Lewy body disease" is grammatically confusing and unclear. Is this attempting to define --and an alpha-synuclein associated disease selected from Parkinson's disease and Lewy body disease-- or something else?

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Castillo et al. (WO 98/51302), or over Vitasyn GMBH (DE 19627344 – DWPI Abstract).

Although very unclear, as drafted, a pharmaceutical agent comprising a therapeutically effective amount of "a material" made according to claim 18 is apparently claimed. Dependent claims include dosage ranges thereof.

Castillo et al. teach pharmaceutical compositions (agents) comprising therapeutically effective amount of *Uncaria tomentosa* extract including, e.g., PTI-00703 (see, e.g., pages 28-29, Example 5; pages 32-33, Example 9), which Applicants readily admit contain the various active fractions instantly claimed/disclosed (collectively within fraction PTI-777) – see, e.g., page 3, lines11-15 of the instant specification. Castillo et al. also teach pharmaceutical compositions (agents) comprising therapeutically effective amounts (within the approximate dosage amounts instantly claimed) of various active fractions obtained therefrom (these fractions, as well as PTI-00703, would inherently read upon the "material" defined by claim 31) – see entire document.

Vitasyn GMBH teaches a composition comprising a therapeutically effective amount of epicatechin therein (within the approximate dosage levels instantly claimed) – see DWPI abstract. As readily admitted by Applicants, "fraction J" (one of the preferred separated, collected bioactive fractions obtained in final step q of claim 18) was identified as epicatechin (see, e.g., pages 48-49, Example 16). Since fraction J represents epicatechin, the pharmaceutical product taught by Vitasyn GMBH comprising therapeutically effective amounts of epicatechin therein reads upon the product of instant claims 31-39. It is noted that the Vitasyn GMBH reference does not teach that the composition can be used in the manner instantly claimed; however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Therefore, each of the cited references is deemed to anticipate the instant claims above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 31-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,264,994. Although the conflicting claims are not identical, they are not patentably distinct from each other because both are drawn to a composition (agent) comprising a therapeutically effective amount (including within the approximately instantly claimed dosage range) of plant matter (material) obtained from *Uncaria tomentosa* (cat's claw) having amyloid inhibitory activity (i.e., useful for treating amyloid diseases).

Claims 31-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 09/938,987; and over claims 9-15 of copending Application No. 10/099,637. Although the conflicting claims are not identical, they are not patentably distinct from each other because each are drawn to compositions (agents) comprising therapeutically effective amounts (including within the approximately instantly claimed dosage range) of plant matter (material) – such as (for Appl. '637) epicatechin (which inherently defines instantly claimed "fraction J" – see discussion above) obtained from *Uncaria tomentosa* (cat's claw) having amyloid inhibitory activity for treating amyloid diseases.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (703) 305-7114. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (703) 306-3220. The Group receptionist may be reached at (703) 308-0196. The fax number for art unit 1654 is (703) 872-9306.

Christopher R. Tate
Primary Examiner, Group 1654